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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,786	08/27/2003	Jian Ni	1488.130000B/EKS/EJH	5264

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STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 NEW YORK AVE., N.W.
WASHINGTON, DC 20005

EXAMINER	
KAUFMAN, CLAIRE M	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 05/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/648,786	NI ET AL.	
	Examiner	Art Unit	
	Claire M. Kaufman	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-77* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 8-30, 33-56, 59-77*, drawn to method of treating a disease by administering an agonist anti-DR4 antibody and additional therapeutic agent, to the composition comprising an agonist anti-DR4 antibody and additional therapeutic agent, and method of causing death of a cell expressing a DR4 protein or extracellular domain thereof by contacting the cell with an agonist anti-DR4 antibody classified in class 424, subclass 143.1.

II. Claims 1-3, 6, 7, 9-28, 31, 32, 34-54, 57, 58, 60-75, drawn to method of treating a disease by administering an antagonist anti-DR4 antibody and additional therapeutic agent, and additional therapeutic agent and to the composition comprising an antagonist anti-DR4 antibody and additional therapeutic agent , classified in class 424, subclass 143.1.

*Claims 76-77 require causing cell death and so were put in Group I with the agonist antibody and methods of using it. If Applicants feel claims 76-77 also belong in Group II, the reasons should be set forth in Applicants' response.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are directed to related methods of treating diseases using a DR4 antibody and therapeutic agent. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the agonist and antagonist antibody are mutually exclusive, not capable of treating the same condition since one will activate the DR4 receptor and one will prevent the receptor's activation. The methods using the agonist antibody cannot be used with the methods using the antagonist antibody since each method must necessarily have an opposite goal. For these reasons, the inventions are not obvious variants.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, have recognized divergent subject matter, and because each invention requires a separate non-coextensive search since the method of treatment of each invention is distinct due to the opposite effects of the antibody required by the method of each invention, restriction for examination purposes as indicated is proper.

Species

This application contains claims directed to the following patentably distinct species: method of treating: (1) graft *vs* host disease (claims 1- 25 and 75), (2) viral infection (claims 1-25), (3) immunodeficiency (claims 1-25), (4) autoimmune disorder (claims 1- 25 and 75), (5) inflammation (claim 75) and (6) cancer (claims 26-50 and 75). The species are independent or distinct because each disease requires a separate search since each has different causes, symptoms and cures.

This application contains claims directed to the following patentably distinct species: second therapeutic agent: (i) TRAIL, (ii) a TNF, (iii) a TNF blocking agent, (iv) an immunosuppressive agent, (v) an antibiotic, (vi) an anti-inflammatory agent, (vii) a chemotherapeutic agent, (viii) a cytokine.

For (ii) a TNF:

For (iii) a TNF blocking agent, an antibody that binds: (a) TNF-α, (b) TNF-β, (c) TNF-γ, (d) TNF-γ-α, and (e) TNF-γ-β,;

For (iv) an immunosuppressive agent: (a) clyclosporin, (b) cyclophosphamide, (c) methylprednisone, (d) prednisone; (e) azathioprine; (f) FK-506; and (g) 15-deoxyspergualin.

For (viii) a cytokine: (a) IL-2; (b) IL -3; (c) IL-4; (d) IL -5; (e) IL-6; (f) IL-7; (g) IL-10; (h) IL-12; (i) IL-139 U) IL-15; and (k) IFN- γ.

For (vii) a chemotherapuetic agent : (a) an alkylating agent; (b) an antimelbolite; (c) a farnesyl transferase inhibitor; (d) a mitotic spindle inhibitor; (e) a nucleotide analog; (f) a platinum analog; (g) a topoisomerase inhibitor, (h) ibritumomab tiuxetan (Zevalin™); (i) imatinib mesylate (Gleevec®); (j) bortezomib (Velcade™); and (k) a smac peptide or polypeptide.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic for treatment of disease. Claims 1 and 3-19 are generic with respect to the second therapeutic agent.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (571) 272-0873. Dr. Kaufman can generally be reached Monday, Tuesday, Thursday and Friday from 9:30AM to 2:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached at (571) 272-0835.

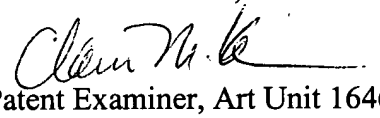
Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Official papers filed by fax should be directed to (571) 273-8300. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or

applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Claire M. Kaufman, Ph.D.



Patent Examiner, Art Unit 1646

May 4, 2006